

Appl. No. 10/065,960
Docket No. 125517/GEM-0071

REMARKS / ARGUMENTS

Status of Claims

Claims 1-10, 13-16, 18, 20-26, 29-35 and 37 are pending in the application. Claims 1-10, 13-16, 18, 20-26, 29-35 and 37 stand rejected. Applicant has amended Claims 1-6, 10, 16, 18, 21, 25, and 37, and has added new Claim 39, leaving Claims 1-10, 13-16, 18, 20-26, 29-35, 37 and 39 for consideration upon entry of the present Amendment.

Applicant respectfully submits that the rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) have been overcome, that no new matter has been entered, and that the application is in condition for allowance.

These amendments and accompanying remarks were not presented earlier because Applicant did not fully appreciate the nature of the Examiner's position until the Applicant was advised in more detail of the position by the final rejection, which introduced new grounds of rejection. The claim amendments presented herein, which Applicant respectfully requests entry thereof, should require only a cursory review by the Examiner as they are primarily directed to clarifying the claimed invention.

Applicant Submits That The Finality Of The Present Office Action Is Premature

Applicant respectfully submits that "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)...." (emphasis added) MPEP §706.07(a)

The Examiner asserts that Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. (Present Paper, Page 11).

Applicant respectfully disagrees.

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Applicant submits that Claims 1, 10, 16, and 18, are presently rejected under 35 USC §103, and were rejected under different grounds (35 USC §102) in the previous action. However Applicant respectfully submits that none of Claims 1, 10, 16, and 18 were amended in the previous response. Furthermore, Applicant submits that no rejections are based on information submitted via an information disclosure statement filed during the period set forth in 37 CFG 1.97(c).

Accordingly, applicant submits that Claims 1, 10, 16, and 18 were rejected under a new ground of rejection that was neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement. Therefore, Applicant respectfully submits that the finality of the present office action is premature, and therefore requests withdrawal of the finality of the present office action in order to allow Applicant the opportunity to fully respond to the new grounds of rejection provided by the Examiner.

Rejections Under 35 U.S.C. §102(b)

Claim 21 stands rejected under 35 U.S.C. §102(b) as being anticipated by Scanlon (U.S. Patent No. 5,853,005 hereinafter Scanlon).

Applicant traverses this rejection for the following reasons.

Applicant respectfully submits that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, *in a single prior art reference*." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Moreover, "[t]he identical invention must be shown in as complete detail as is contained in the *** claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Furthermore, the single source must disclose all of the claimed elements "arranged as in the claim." *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference.

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Titanium Metals Corp. v. Banner, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985).

Dependent claims inherit all of the limitations of the respective parent claim.

Regarding Independent Claim 21

Applicant has amended Claim 21 to now recite, inter alia: "...a *non-electrical sensor from a group consisting of a force sensor, and an ultrasonic sensor* ...". No new matter has been added, as antecedent support may be found in the originally filed application, such as originally filed Claim 21, for example.

In alleging anticipation of Claim 21, the Examiner remarks "...The transducer may be a force, or pressure, transducer that provides an output proportional to pressure changes (col. 2, lines 35-44). Measurement based on pressure *can be equated* with measurement based on force because pressure by definition is the *exertion of force upon a surface*." (emphasis added) [paper 20070423]

Applicant finds Scanlon to disclose "...the sensor pad is liquid-filled with a pressure transducer arranged in communication with the *internal volume* of the pad such that forces applied to the pad by the object cause *pressure changes* which are detected by the *pressure transducer*. The pressure transducer provides an *output proportional to the pressure changes*..." (emphasis added) [Scanlon, col. 2, lines 31-36].

Here, Applicant submits that Scanlon discloses a pressure transducer that is responsive to change in *pressure of a fluid within a pad*. While it is possible that a change in pressure can be equated to an exertion of a force upon a surface, Applicant respectfully submits that in order for the changes in pressure to be equated with measurement based on force (as alleged by the Examiner), *a surface* having *a specific surface area* must be known and provided. Scanlon teaches that the *pressure transducer* must be disposed within a pad filled with fluid.

Applicant respectfully submits that a *pressure transducer disposed within a fluid filled pad* (presumably having a given, defined surface area) as disclosed by Scanlon is *substantially different* from the claimed *force sensor*, as the *force sensor* provides an *output proportional to force changes*, independent of any *defined surface area* and

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therefore does not require a fluid filled pad, as does the pressure transducer taught by Scanlon.

Accordingly, Applicant respectfully submits, as set forth above, that disclosure of a pressure transducer falls wholly short of anticipating a force sensor, and further submits that Scanlon is absent disclosure of the now claimed "...a non-electrical sensor from a group consisting of a force sensor, and an ultrasonic sensor..."

Accordingly, Applicant submits that Scanlon does not disclose each and every element of the claimed invention arranged as in the claim, and absent anticipatory disclosure in Scanlon of each and every element of the claimed invention arranged as claimed, Scanlon cannot be anticipatory. Therefore, Applicant respectfully submits that the Examiner's rejection under 35 U.S.C. §102(b) has been overcome, and requests that the Examiner reconsider and withdraw this rejection.

Rejections Under 35 U.S.C. §103(a)

Claims 1, 7-10, 13-15, 18 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Schlager et al. (U.S. Patent No. 6,024,705, hereinafter Schlager).

Claims 16, 24-26, 31, 34-35 and 37 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Scanlon.

Claims 2-6, 22-23, 29-30 and 32-33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schlager in view of Scanlon.

Applicant traverses these rejections for the following reasons.

Applicant respectfully submits that the obviousness rejection based on the References is improper as the References fail to teach or suggest each and every element of the instant invention in such a manner as to perform as the claimed invention performs. For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). The Examiner must meet the burden of establishing that all elements of the invention are taught or suggested in the prior art. MPEP §2143.03.

Applicant respectfully submits that "[a] prima facie case of obviousness is

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established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art," (emphasis added), *In re Bell*, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 189 USPQ 143, 147 (CCPA 1976)), and that where the reference cited by the Examiner is combined with the teachings of the present invention for the purpose of obviating the present invention, such use of a reference is improper, and the reference cannot be used as a prima facie case of obviousness with respect to the present invention.

Additionally, Applicant respectfully submits that a prima facie case of obviousness cannot be supported by a proposed modification that would render the prior art invention being modified unsatisfactory for its intended purpose. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984); MPEP §2143.01.

Dependent claims inherit all of the limitations of the respective parent claim and any intervening claim.

Regarding Examiner's Paragraph 5

Regarding Independent Claims 1, 10, and 18 more specifically

Applicant has amended Claims 1 and 18, to now recite, inter alia, "...gating using the acquired information...".

Applicant has amended Claim 10 to now recite, inter alia, "...gating using the acquired acceleration waveform...".

No new matter has been added, as antecedent support may be found in the application as originally filed, such as at paragraph [0018] and Figure 2, for example.

To allege obviousness of Claims 1, 10, and 18, the Examiner looks to Schlager and states that it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize the non-electrical sensor to acquire information for cardiac gating because the SCG waveform contains information for determining intervals between the atrial depolarization and ventricular stimulation pulse events. (Present Office Action Paper, page 4).

In view of the claim amendments, Applicant respectfully disagrees that Schlager is useful for rejecting the subject claims as alleged by the Examiner.

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Applicant finds Schlager to disclose "...SCG waveform coefficients are then processed in a pattern recognition process unit for classification of the SCG waveform and *producing an output* in one program which *identifies a patient with myocardial ischemia...*" (emphasis added) [Schlager, col. 6, lines 15-17].

Applicant respectfully submits that the data analysis for producing an output to *identify* a patient with *myocardial ischemia* by way of SCG waveform coefficients is *substantially different* than the data analysis for *gating* as claimed by the amendments set forth above.

Applicant respectfully submits that Schlager is absent any teaching or suggestion of the now claimed "...*gating* using the acquired (information / acceleration waveform)..." Accordingly, Applicant submits that Schlager fails to disclose each and every element of the claimed invention arranged in a manner to perform as the claimed invention performs, and therefore cannot support a prima facie case of obviousness.

Regarding Independent Claim 18 more specifically

To allege obviousness of Claim 18, the Examiner asserts "an accelerometer is an adaptable device and is fully capable of being arranged on a wrist of a patient to yield information for peripheral pulse gating" and looks to Schlager at col.1, lines 10-27 and col. 5, lines 35-60 (Present Paper, page 5). Applicant respectfully disagrees.

Applicant finds Schlager to teach "...a suitable accelerometer, is *secured to the sternum area of a patient's chest* just above the xiphoid heart process location ...The sensor 1 is preferably a sensitive and stable accelerometer providing a signal *responsive to chest wall vibrations*." [Schlager, col. 5, lines 40-45]

Here, Applicant finds Schlager to teach an accelerometer that is *secured to a patient's chest* and is *responsive to chest wall vibrations*, in order to identify a patient with myocardial ischemia (as discussed above). Applicant submits that modification of the accelerometer of Schlager to be located *upon the wrist* of the patient, as suggested by the Examiner, would render the accelerometer of Schlager to be unsatisfactory for its intended purpose, as the *accelerometer located upon the wrist* of the patient will not necessarily be *responsive to chest vibrations*, and therefore will not be suitable for

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producing an output which identifies a patient with myocardial ischemia, as taught by Schlager.

Accordingly, Applicant respectfully submits that modification of the accelerometer, secured to a patient's chest and responsive to chest wall vibrations as taught by Schlager, to be located upon the wrist of the patient, would render Schlager unsatisfactory for its intended purpose, and that a prima facie case of obviousness cannot be supported by a proposed modification that would render the prior art invention being modified unsatisfactory for its intended purpose.

Regarding Claim 7 more specifically

To allege obviousness of Claim 7, the Examiner asserts that teaching by Schlager of linear prediction coefficients permit the SCG analysis instrument to provide the claimed *determining timing of a gating signal to be prior to displacement of a body part of a patient*. (Present Paper, Page 5). Applicant respectfully disagrees.

Applicant finds Schlager to teach "linear prediction coefficient determination function 11 in which the LPA coefficients are *calculated for time segments of the SCG wave...* The average and standard deviation of each of these coefficients are preferably determined and *segments with coefficients beyond a two standard deviation range are discarded*. This establishes SCG waveforms as a series of numerical LPA coefficients for *processing of the total waveform for classification or for estimation purposes ...* The output includes a *probability figure indicating the strength of the certainty of the diagnosis...*" [Schlager, col. 6, lines 2-21]

Applicant submits that here Schlager teaches a mathematical manipulation to select segments of a collected waveform that are anticipated to provide increased accuracy of a diagnostic determination of *the total waveform* (which must therefore occur *following* data acquisition of the *total waveform*) and to *predict an accuracy of the diagnostic determination*, which Applicant submits is *substantially different* from the claimed *determining timing of a gating signal to be prior to displacement of a body part of a patient*. Therefore, Applicant submits that the *accuracy prediction (following data acquisition)* of Schlager fails to teach or suggest the claimed *gating signal determination*

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prior to body part displacement.

Accordingly, Applicant submits that Schlager fails to teach or suggest each and every element of the claimed invention arranged to perform as the claimed invention performs, and that absent such teaching Schlager cannot support a prima facie case of obviousness.

Regarding Claim 13 more specifically

To allege obviousness of Claim 13, the Examiner acknowledges the Schlager fails to disclose a jerk waveform and determining a salient-peak of the jerk waveform, and alleges that the mathematical modeling and computer processing is capable of performing the function as claimed. (Present Office Action Paper, page 6) The Examiner alleges that it would be obvious to one with ordinary skill in the art to perform calculations to provide a trigger for cardiac gating, and looks to col. 12 lines 35-67 and col. 13, lines 1-39 of Schlager for such motivation. Applicant respectfully disagrees.

Applicant finds Schlager to teach "Linear prediction analysis is a well known form of mathematical modeling used to represent a waveform by a relatively small number of model coefficients...[yielding] a mathematical model that will contain substantially all, if not all, of the information resident in the original waveform...to determine the ak coefficients so as to minimize the mean square error, E... the partial derivative of E with respect to each coefficient...should be zero" (emphasis and clarification added)[Schlager, col. 12, line37 -- col. 13, Line 10]

Here, Applicant finds Schlager to teach a mathematical modeling to represent a waveform, and calculations including a partial derivative to reduce an error of the model that represents the waveform. Applicant respectfully submits that such representation and calculations as taught by Schlager are substantially different from and wholly absent any teaching or suggestion to arrive at the claimed calculating a first derivative of the acceleration waveform to obtain a jerk waveform, determining a salient-peak of the jerk waveform, and utilizing the salient-peak as a trigger point for cardiac gating.

The Examiner states that it would be obvious to perform calculations to provide a

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trigger for cardiac gating. Even following the Examiner's own reasoning Applicant finds no suggestion within the prior art for the purpose of performing the claimed calculations for gating. As such, Applicant submits that absent hindsight one skilled in the art would not be motivated to do what Applicant has done for the purposes disclosed in the instant application itself.

Accordingly, Applicant submits that Schlager is absent any teaching, suggestion, or motivation to arrive at the claimed invention without hindsight and while maintaining Schlager to be satisfactory for its intended purpose. As such, Applicant submits that the modification of Schlager as suggested by the Examiner cannot be used to establish a prima facie case of obviousness against the claimed invention.

Regarding Examiner's Paragraph 6

Regarding Independent Claims 16, 25, and 37 more specifically

Applicant has amended Claims 16, 25, and 37 to now recite, inter alia: "...gating using the acquired information..." No new matter has been added, as antecedent support may be found in the application as originally filed, such as at paragraph [0018] and Figure 2, for example.

To allege obviousness of Claims 16, 25, and 37, the Examiner looks to Scanlon, and states that it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize the non-electrical sensor to acquire information for gating because the output signal based on pressure fluctuation would be useful in determining the time when the best image of an organ is taken. (Present Office Action Paper, page 8). Applicant respectfully disagrees.

Applicant finds Scanlon to disclose "...processing output signals from the transducer caused by pressure fluctuations in the pad such as may be caused by biological activity of a living organism in contact with the pad...Aural interpretation of the sensor output and acoustic signature analysis can indicate cessation of breathing or heartbeat, or other conditions, such as a partially obstructed airway, sucking chest wound, hyperventilation, asthma, murmurs..." [Scanlon, col. 4, lines 42-45 and col. 6, line 66 -

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col. 7, line 3]

Here, Applicant finds Scanlon to teach diagnosis of various physical conditions via acoustic interpretation. Applicant respectfully submits that such acoustic diagnostic processing of output signals as taught by Scanlon fails to provide any teaching or suggestion of *gating* as claimed by the present invention.

Applicant respectfully submits that Scanlon is absent any teaching or suggestion of the now claimed "...gating using the acquired information..." Accordingly, Applicant submits that Scanlon fails to disclose each and every element of the claimed invention arranged in a manner to perform as the claimed invention performs, and therefore cannot support a prima facie case of obviousness.

Furthermore, Applicant respectfully submits that output signal processing as taught by Scanlon is *substantially different* from, and wholly absent any teaching or suggestion to arrive at, the claimed *gating using the acquired information*.

The Examiner states that it would be obvious to utilize the non-electrical sensor to acquire information for gating. Even following the Examiner's reasoning, Applicant finds no suggestion within the prior art for the purpose of utilizing the output signal based on pressure for gating. As such, Applicant submits that absent hindsight one skilled in the art would not be motivated to do what Applicant has done for the purposes disclosed in the instant application itself.

Accordingly, Applicant submits that Scanlon is absent any teaching, suggestion, or motivation to arrive at the claimed invention without hindsight. As such, Applicant submits that the modification of Scanlon as suggested by the Examiner cannot be used to establish a prima facie case of obviousness against the claimed invention.

Regarding Examiner's Paragraph 8

In view of Examiner's paragraph 8 being directed only to dependent claims, Applicant submits that Claims 2-6, 22, 23, 29, 30, 32 and 33 are allowable at least for the reason that they depend from allowable claims as submitted by Applicant in Applicant's remarks/arguments set forth above.

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In view of the foregoing, Applicant submits that the References fail to teach or suggest each and every element of the claimed invention and are therefore wholly inadequate in their teaching of the claimed invention as a whole, fail to motivate one skilled in the art to do what the patent Applicant has done, fail to teach a modification to prior art that does not render the prior art being modified unsatisfactory for its intended purpose, fail to motivate one skilled in the art to do what the patent Applicant has done, with or without hindsight, and disclose a substantially different invention from the claimed invention and therefore cannot properly be used to establish a prima facie case of obviousness. Accordingly, Applicant respectfully requests reconsideration and withdrawal of all rejections under 35 U.S.C. §103(a), which Applicant considers to be overcome.

Regarding New Claim 39

Applicant has added new Claim 39, which depends from Claim 1, to now claim originally disclosed but previously unclaimed subject matter. No new matter has been added as antecedent support may be found in the application as originally filed, such as at originally filed Claim 13, for example.

In view of the amendment and remarks set forth above regarding the allowability of Claim 1, Applicant submits that new Claim 39 is directed to allowable subject matter and respectfully requests entry and notice of allowance thereof.

Notwithstanding Applicant's request set forth above to remove the finality of the present office action for being premature, in light of the foregoing remarks and amendments, Applicant respectfully submits that the proposed amendments and arguments comply with 37 C.F.R. §1.116 and should therefore be entered, and with their entry that the Examiner's rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) have been overcome, and that the application is now in condition for allowance. Such action is therefore respectfully requested.

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If a communication with Applicant's Attorneys would assist in advancing this case to allowance, the Examiner is cordially invited to contact the undersigned so that any such issues may be promptly resolved.

The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment, to Deposit Account No. 07-0845.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for extension of time, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-identified Deposit Account.

Respectfully submitted,

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